K000529

MAR 21 2000

510 (k) SUMMARY FOR FREEDOM OF INFORMATION

DATE PREPARED: FEBRUARY 8, 2000

SUBMITTER:
The LifeStyle Company, Inc.
712 Ginesi Drive
Morganville, NJ 07751
FDA Registration No: 2249258

OFFICIAL CORRESPONDENT:
Dr. Martin Riehm
The LifeStyle Company, Inc.
712 Ginesi Drive
Morganville, NJ 07751
Phone: 1-732-972-8585
Fax: 1-732-972-9205

REASON FOR 510(K) SUBMISSION:
Changed indication for use

DEVICE IDENTIFICATION:

TRADE NAME: The LifeStyle MV2™ Toric (polymacon) Soft (Hydrophilic) Multifocal Contact Lens for Daily Wear (clear and tinted)

COMMON NAME: Contact lens

CLASSIFICATION NAME: Soft (hydrophilic) Contact Lens
Class II - Daily Wear Contact Lens

DEVICE PANEL AND PRODUCT CODE:
Ophthalmic 86 LPL
Lens, Contact (Other Material) Daily Wear

PERFORMANCE STANDARDS:
None

DEVICE DESCRIPTION:

The LifeStyle MV2™ Toric (polymacon) Soft (Hydrophilic) Multifocal Contact Lens for Daily Wear (clear and tinted) is substantially equivalent to the predicate lens, The LifeStyle MV2™ (polymacon) Soft (Hydrophilic) Multifocal Contact Lens for Daily Wear (clear and tinted), which is indicated for use on eyes that may exhibit astigmatism up to 2.00 Diopters that does not interfere with visual acuity. By the addition of a back toric surface, the new lens, **The LifeStyle MV2™ Toric (polymacon) Soft (Hydrophilic) Multifocal Contact Lens for Daily Wear (clear and tinted)**, may be used on eyes **with astigmatism of up to 4.00 diopters**. The new lens is otherwise identical to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2000

Mr. Martin Riehm
The LifeStyle Co., Inc.
712 Ginesi Dr.
Morganville, NJ 07751

Re: K000529
Trade Name: The LifeStyle MV2™ Toric (polymacon) Soft (Hydrophilic) Multifocal Contact Lens for Daily Wear (clear and tinted).
Regulatory Class: II
Product Code: 86 LPL
Dated: February 16, 2000
Received: February 17, 2000

Dear Mr. Riehm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K000529

Device Name: The LifeStyle MV2™ Toric (polymacon) Soft (Hydrophilic) Multifocal Contact Lens for Daily Wear (clear and tinted)

Indications for Use: The LifeStyle MV2™ Toric (polymacon) Soft (Hydrophilic) Multifocal Contact Lens for Daily Wear (clear and tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astigmatism up to 4.00 diopters in aphakic and not-aphakic persons with non-diseased eyes.

Eyecare practitioners may prescribe the lens for daily wear in a Planned Replacement Program. The lens may be disinfected using heat, chemical, or hydrogen peroxide disinfection systems.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000529